

TIME REQUIREMENT FOR AIR

FDA's timing is based on their receiving, analyzing, and returning a FDA assigned Prior Notice (PN) number all before the time frame set forth in their interim final rules, for air that outside minimum time is **FOUR HOURS**.

To ensure that we have an FDA response complete with their PN number, our goal is to transmit prior notice information **at least one hour before** the FDA's required four-hour minimum response time frame. Due to the volume of FDA Food related shipments that PBB handles; we will require that all information be made available to PBB at **least one additional hour** for a one line simple entry (**total six hours prior to shipments arrival**). Additional times will be required based upon complexity of entry, completeness of necessary information, and hours of operation as noted below.

A major concern is the fact that most international airfreight shipments arrive over night, PBB's general operations time for air shipments is 9 am – 5 pm local time, which means that PBB will require that the documents for any shipment due to arrive that evening during the course of previous day with ample time to prepare the PN for FDA.

There is no simple way of providing an outline of time expectations for air shipments, we have produced an outline below, however, for example a flight due to arrive at 1am would not be addressed if documentation were provided using those guidelines alone. Time needs to start at 5pm the business day prior to arrival.

We have determined that there are four levels of complexity when dealing with FDA Food products:

- 1) Fully set up information in PBB's client record database well prior to current shipment
- 2) Documentation reflects complete and proper information as it relates to prior notice, but that information isn't resident in PBB's system
- 3) Certain required prior notice data elements are missing, but are able to be developed from the available information (e.g. product code)
- 4) PBB does not have the necessary information to process prior notification and client contact must occur to obtain prior to entry

USING CASE 1 ABOVE:

For every eight (8) additional lines, or part thereof, we will require sixty (60) additional minutes (**seven (7) hours minimum**).

USING CASE 2 ABOVE:

For every four (4) additional lines, or parts thereof, we will require sixty (60) additional minutes (**seven (7) hours minimum**).

USING CASE 3 ABOVE:

For every two (2) additional lines, or part thereof, we will require sixty (60) additional minutes (**seven (7) hours minimum**).

USING CASE 4 ABOVE:

Documentation must be received **one business day prior to shipping**, and once missing information is obtained shipment is then subject to the same time frames as scenario three above.

Obviously, there will be a need for shippers, importers, carriers, and PBB to have an understanding of exactly what type of shipment is being forwarded. It cannot be stressed too much that it is in everyone's interest to ensure that most food related transaction fit into the first scenario noted above. PBB should have a full and complete database of products to be shipped well in advance (days – weeks) of the movement of freight on a particular day.

This will ensure that the minimum amount of time necessary to input, transmit and receive this information to and from CBP – FDA.

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If it is not the case, and PBB is not made aware of the shipment with ample enough time to meet any of the three other scenarios (2 – 4) there is a significant likelihood that the shipment information will not be transmitted to, and returned from, CBP – FDA within the time required and the possibility exists that the shipment will be refused or detained at the border at your expense.

PBB can, and will, make our tracing notes available to our clients so that they can monitor their own PN transactions, if they care to hold shipping freight until a PN number is issued. PBB can, and will, monitor transactions for our clients, at an additional fee.

Further, Prior Notice approval is not to be considered an FDA “May Proceed” these two issues are separate and distinct items. Since, all Food shipments there is a very real possibility that a shipment may have PN approval, received CBP release, and not have a “May Proceed” issued.

This could mean that an FDA regulated article could be delivered to a U.S. address prior to FDA determining admissibility.

ADMISSIBILITY

The importer of record is responsible to ensure that the goods are held “intact” pending receiving final FDA admission determination. PBB can, and will, make our tracing notes available to our clients so that they can monitor their own transactions. PBB can, and will, monitor transactions for our clients, at an additional fee.

PBB will not be held responsible for any shipments that receive FDA Prior Notice approval, CBP release, and are not held pending FDA admissibility under any circumstances.

Remember, the FDA penalty for non-compliance of admissibility review is three times the value of the goods shipped.